UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,937	12/28/2001	Philip R. Westbrook	3784	3784

24201 7590 10/06/2003

FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/040,937	Applicant(s) WESTBROOK ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51,53,62-65 and 68-77* is/are rejected.

7)☒ Claim(s) *52,54-61,66 and 67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim R jections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-48, and 70-72 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 26 recite the limitation "system that is affixed on said patient's head". Claims 25 and 48 recite the limitation "system is affixed to the patient". Claim 36 recites the limitation " pulse oximetry sensor, said power source, and said storage memory are affixed on said patient's body". Claim 70 recites the limitation "sensors and power means are affixed on said patient's body". In each case, the human body (patient, patient's body), or part thereof (patient's head), is non-statutory subject matter and cannot positively be claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 22, 27, and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 -18 and 33-35 recite the limitation "the level of oxyhemoglobin desaturation" on lines 1-2 of each claim. There is insufficient antecedent basis for this limitation in the claims.

Claims 23, 27, and 53 recite the limitation "the patient anthropomorphic and clinical information". There is insufficient antecedent basis for this limitation in the claim.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "anthropomorphic" in claims 23, 27, and 53 seems to be used by the claims to mean "measured", while the accepted meaning is "attributing human characteristics to non-human things." The term is indefinite because the specification does not clearly redefine the term.

Claim 32 recites the limitation "the pulse oximetry data signal values" on lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 11, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowers et al. Bowers discloses a sleep apnea monitor 10 including a reflectance type pulse oximetry sensor 18 that detects oxyhemoglobin saturation and pulse rate, a sensor 20 indicating the position and movement of the head of the patient, a microphone 16, and a patient respiratory airflow detector 14, comprising a pressure transducer, and storage memory 30 for recording data from the sensors. The sensors 14, 16, 18, 20 are affixed on the patient's head. A data transfer interface 24 delivers to an external computing device 26 data signals from the sensors 14, 16, 18, and 20, and computes SaO_2 measurements therefrom. The pulse oximetry sensor 18 applies positive pressure on the patient. Headgear 12 holds the sensors 14, 16, 18, 20 in place via adjustable straps 40 and 42 (figs. 1-5 and 14).

Claims 1, 2, 5-8, 14-16, 21, 26, 30-33 are rejected under 35 U.S. C. 102(b) as being unpatentable over Yaminishi et al. Yaminishi discloses a reflectance type pulse oximetry sensor 1 for determining blood oxygen saturation and pulse rate. The system includes computing circuitry 6, which stores the saturation and pulse rate data in a storage memory 12. Computing circuitry/expert system 6 determines desaturation events according to a variable threshold, and classifies the event into either central or obstructive apnea. The computing/expert system 6 generates a patient report on unit 20, marking central apnea events with a "C" and obstructive apnea with an "H".

Regarding the limitation "a physiological monitoring system that is affixed on said patient's head", the applicant should note that this is merely intended use language,

which cannot be relied upon to define over Yaminishi, since the reference teaches all of the claimed elements and their recited relationships.

Claims 1, 2, 5-8, 12, 14-16, 20, 36, 39, 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Clauson et al. Clauson et al. discloses a respiratory monitoring system including a reflectance type pulse oximeter 17 attached to the patient's head for detecting oxygen saturation of arterial blood and pulse rate. Oximeter 17 outputs a signal via data transfer interface 21 to computing system 22, and may be in the form of an ear clip, thereby applying positive pressure to the patient. Computing system 22 stores data in storage memory 23, samples the information, and compares it to variable thresholds. The computing system 22 identifies a respiratory event, actuating a neuromuscular stimulation device 26 in response to detecting signals indicating oxyhemoglobin desaturation, where the saturation level is below an acceptable level. A battery 41 supplies power to the system. An alternate embodiment provides adjustable band 156 (figs. 1, 3, 4; also, col. 8, line 30-col. 9, line 17).

Claims 26, 28, 29, and 30 are rejected under 35 U.S. C. 102(e) as being anticipated by Karakasoglu et al. Karakasoglu discloses a head mounted system comprising a reflectance type pulse oximeter S6 for detecting oxygen desaturation and may also sense heart rate, microphone 56, head position sensor S7, storage memory 67 for storing signals from the sensors, and power means 71. Signals from the sensors S6, 56, S7, 71 are output, via data transfer interface 111, to computing system 112 and expert system 106-108 that determines patterns in the acquired data to determine

respiratory events. The system also outputs an index that counts the number of abnormal respiratory events

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers et al. in view of Sasagawa. Bowers lacks a transmission coil. However, Sasagawa discloses that physiological signals may be transmitted either via a wire or wirelessly. In the case of wireless communication, a transmission coil 6 may be provided in a transmitter unit (col.1; fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to wirelessly transmit the physiological signals in Bowers et al., since Sasagawa teaches that wireless communication and communication via a wire are functionally equivalent.

Claims 37, 38, 70-73, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Bowers et al. Clauson lacks a patient sensor indicating position and movement of the patient's head and a microphone producing a signal indicating detected patient sounds. However, Bowers discloses a sleep apnea monitor 10 including a reflectance type pulse oximetry sensor 18, a sensor 20 indicating the position and movement of the head of the patient, a microphone 16, and a patient respiratory airflow detector 14, comprising a pressure transducer (figs. 1-5

and 14). Therefore, it would have been obvious to use a microphone and a head movement sensor with the system of Clauson since Clauson describes using additional sensors in its system (col. 5, lines 14-23), and Bowers describes a microphone and head movement sensor as being suitable sensors for an apnea monitoring system.

Claims 41 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Coetzee. Clauson lacks applying a window median filter or other multiple data sample values averaging technique. However, Coetzee discloses a pulse oximetry device in which blood oxygenation signals undergo a final stage of processing comprising a filter 334, where the first filter stage uses a window median filter that replaces a current data sample value with a median value selected form a predetermined number of data sample. The output of the median filter is subsequently filtered using another nonlinear predictor-corrector filter (fig. 3). Therefore, if would have been obvious to one of ordinary skill in the art to combine the pulse oximetry device of Coetzee with the oximeter of Clauson in order to eliminate noise from the pulse oximetry signals, thereby obtaining more accurate results.

Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Baker, Jr. Clauson lacks applying a multiple data sample value averaging technique. However, Baker describes an oximetry system 100 in which seven metrics are determined based on the pulse oximetry signals for use by the neural net 306 to determine whether the oximetry sensor is properly connected to the patient and to generate a value representing the probability thereof. The filtered (step 208) and normalized (step 210) pulse oximetry signals are averaged with a single-pole IIR filter to

determine a metric 2. A determination of a metric 3 is also determined which involves using a whitening filter on the filtered and normalized pulse oximetry signals and then averaging the metric with a single-pole IIR filter with an appropriate time constant (figs. 1-3; col. 6, line 58-col. 7, line 48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the pulse oximetry system of Baker, Jr. with the oximeter of Clauson in order to verify proper application of the pulse oximetry sensor, thereby ensuring more accurate results.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Lynn. Clauson recites that oximetry information is sampled and compared to preprogrammed thresholds, but is silent as to which information is used. However, Lynn teaches a sleep apnea diagnosing device in which the slope of the oxygen saturation level is calculated by means for calculating a slope of said desaturation event representing a rate of change per unit time of fall of oxygen saturation. This slope is then compared with a threshold to indicate sleep apnea (col. 4, lines 16-31; figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the rate of change of pulse oximetry data to identify desaturation of Clauson et al., since Clauson recites comparing oximetry information with thresholds to identify events, and Lynn discloses the rate of change of blood saturation may be used to identify such events.

Claims 49-51, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Bowers et al. Clauson uses a finger cuff or ear clip pulse oximeter, but fails to mention applying the sensor to the patient's

forehead. However, Bowers teaches placing a pulse oximetry sensor 18 to the forehead of a patient, where the forehead responds to changes in oxygen saturation levels substantially more quickly than extremities such as a fingertip (figs. 1, 3-5; col. 4, lines 22-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a forehead oximeter as the oximeter of Clauson et al. since Bowers teaches that a forehead oximeter is more accurate than one placed on a fingertip, in order to obtain more accurate pulse oximetry readings.

Claims 62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Bowers et al. as applied to claims 49-51, 68, and 69 above, and further in view of Coetzee. Clauson, as modified, lacks applying a moving window median filter or other multiple data sample value averaging technique. However, Coetzee discloses a pulse oximetry device in which blood oxygenation signals undergo a final stage of processing comprising a filter 334, where the first filter stage uses a window median filter that replaces a current data sample value with a median value selected form a predetermined number of data sample. The output of the median filter is subsequently filtered using another nonlinear predictor-corrector filter (fig. 3). Therefore, if would have been obvious to one of ordinary skill in the art to combine the pulse oximetry device of Coetzee with the oximeter of Clauson, in view of Bowers et al., in order to eliminate noise from the pulse oximetry signals, thereby obtaining more accurate results.

Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Bowers et al., as applied to claims 49-51, 68, and 69, above,

and further in view of Baker, Jr. Clauson, as modified, lacks applying a multiple data sample value averaging technique. However, Baker describes an oximetry system 100 in which seven metrics are determined based on the pulse oximetry signals for use by the neural net 306 to determine whether the oximetry sensor is properly connected to the patient and to generate a value representing the probability thereof. The filtered (step 208) and normalized (step 210) pulse oximetry signals are averaged with a single-pole IIR filter to determine a metric 2. A determination of a metric 3 is also determined which involves using a whitening filter on the filtered and normalized pulse oximetry signals and then averaging the metric with a single-pole IIR filter with an appropriate time constant (figs. 1-3; col. 6, line 58-col. 7, line 48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the pulse oximetry system of Baker, Jr. with the oximeter of Clauson, as modified by Bowers et al., in order to verify proper application of the pulse oximetry sensor, thereby ensuring more accurate results.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clauson et al. in view of Bowers et al, as applied to claims 49-51, 68, and 69, above, and further in view of Lynn. Clauson, as modified by Bowers, recites that oximetry information is sampled and compared to preprogrammed thresholds, but is silent as to which information is used. However, Lynn teaches a sleep apnea diagnosing device in which the slope of the oxygen saturation level is calculated by means for calculating a slope of said desaturation event representing a rate of change per unit time of fall of oxygen saturation. This slope is then compared with a threshold to indicate sleep apnea (col. 4,

lines 16-31; figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the rate of change of pulse oximetry data to identify desaturation of Clauson et al., as modified by Bowers et al., since Clauson, as modified, recites comparing oximetry information with thresholds to identify events, and Lynn discloses the rate of change of blood saturation may be used to identify such events.

Allowable Subject Matter

Claims 17-19, 23, 27, 35, and 53 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 9, 17-19, 22-24, 27, 34, 35, 40, 45, 46, and 74-76 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 52 and 54-61, 66 and 67 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, the prior art fails to teach or suggest a CPAP device that determines and stores the time during which the smart CPAP device is on at a prescribed pressure. Regarding claims 17, 18, 34, 35, 59, 60, 74, and 75, the prior art fails to teach or fairly suggest a respiratory system that determines the occurrence of

oxyhemoglobin desaturation, where the desaturation threshold level is either based on a predetermined relationship between the partial pressure of oxygen and oxyhemoglobin saturation or is at least one of peak or nadir oxyhemoglobin saturation or peak oxyhemoglobin resaturation. Regarding claim 19, the prior art does not teach or fairly suggest a respiratory system that determines the time spent at each of a plurality of oxyhemoglobin saturation levels.

Regarding claim 22, the prior art fails to teach or suggest a respiratory system comprising an expert system that detects patient arousals from at least pulse oximetry or pulse rate signals. Regarding claims 23, 27, and 52-60 the prior art fails to teach or suggest a respiratory system comprising an expert system that analyzes data signals and patient information against a database of sleep apnea risk data.

Regarding claims 24 and 76, the prior art fails to teach or suggest an active pulse oximetry sensor. Regarding claims 40 and 61, the prior art fails to teach or suggest a monitoring system including a pulse oximetry measuring circuit comprising an analog-to-digital converter that receives a difference input signal comprising the difference between the photo diode current and the constant current and produces a measurement current in response, where the constant current is selected such that the difference input signal has an AC component that is substantially equal to its DC component.

With regard to claims 46, 66, and 67, the prior art fails to teach or suggest a monitoring system that identifies SpO_2 data indicating desaturation occurrences by identifying changes in patient arousal.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,148,814 to Clemmer et al.

US Patent No. 6,122,535 to Kaestle et al.

US Patent No. 6,047,201 to Jackson, III

US Patent No. 5,036,852 to Leishman

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm

ROBERT L. NASSER
PRIMARY EXAMINER